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August 22, 2002

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Pages (including this page): 17

Our Ref.: 8932-295

Recipient: Examiner Suzette Jackson

Facsimile Number: 703-746-3354

Company: U.S. Patent and Trademark Office

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Confirmation copy will not follow.

MessageRe: Application No. 09/828,625
Entitled: INTERVERTEBRAL ALLOGRAFT SPACER

As requested, attached please find a copy of the papers filed on July 11, 2002 in connection with the above-referenced application, along with a copy of a date-stamped postcard concerning same.

Please note that the three month suspension of action was requested on the RCE Transmittal, and was referenced in the Communication Submitted with Request for Continued Examination (RCE) Concerning Priority Claim.

If you have any problems regarding this transmission, please contact Seth A. Watkins at (202) 496-4558.

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DC1 - 329715.1

Express Mail to HAND CARRY First Class Mail ()
 Date Mailed July 11, 2002
 Serial No. 09/828,625 Filed April 9, 2001
 Inventor D. Paul et al.
 For Intervertebral Alignment Spacer

- | | |
|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| <input type="checkbox"/> Affidavit/Declaration | <input type="checkbox"/> Fee Address Indication Form |
| <input checked="" type="checkbox"/> Amendment <u>Response Submitted with RCE</u> | <input checked="" type="checkbox"/> Fee Calculation <u>Transmitted with Sheet 1 PE</u> |
| <input type="checkbox"/> Application <u>pages with Exhibit A</u> | <input type="checkbox"/> Issue Fee Transmittal |
| <input type="checkbox"/> <u>claims</u> drawing sheets | <input type="checkbox"/> Notice of Appeal |
| <input type="checkbox"/> Assignment () Cover Sheet | <input type="checkbox"/> Oral Hearing Request/Confirm |
| <input type="checkbox"/> Brief (in triplicate) | <input type="checkbox"/> Petition to Extend Time <u>months</u> |
| <input type="checkbox"/> Declaration & Power of Attorney | <input type="checkbox"/> Petition under 37 C.F.R. <u> </u> |
| <input type="checkbox"/> Executed () Unexecuted () Copy | <input type="checkbox"/> Power of Attorney |
| <input type="checkbox"/> Declaration of Inventor(s) | <input type="checkbox"/> by Assignee () Associate () with Revocation |
| <input type="checkbox"/> Executed () Unexecuted () Copy | <input type="checkbox"/> Request for Correction of Filing Receipt |
| <input type="checkbox"/> Design Application | <input type="checkbox"/> Sequence Listing w/Computer Readable and Paper Copy |
| <input type="checkbox"/> Disclaimer () Disclaimer Fee | <input type="checkbox"/> Small Entity Statement |
| <input type="checkbox"/> Disclosure Statement () Form PTO-1449 | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> w/refs. () w/o refs. | <input type="checkbox"/> Transmittal Letter |
| <input type="checkbox"/> Drawings, Formal | |
| <u> </u> Sheets <u> </u> Figures | |



Other: Request for Continued Examination (RCE) Transmitted; Communication Submitted with RCE Concerning Priority Claim;
 File No. 09322-295 Sender: BMP/SXW

REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995.

See The American Inventors Protection Act of 1999 (AIPA).

Express Mail No.	HAND CARRY
Application Number	09/828,625
Filing Date	04/09/2001
First Named Inventor	D. Paul
Group Art Unit	3738
Examiner Name	S. Jackson
Attorney Docket Number	8932-295

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

NOTE: 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Interim Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.

1. Submission required under 37 C.F.R. § 1.114

- a. ☐ Previously submitted
 - i. ☐ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on _____
(Any unentered amendment(s) referred to above will be entered).
 - ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
 - iii. ☐ Other _____
- b. ☒ Enclosed
 - i. ☒ Amendment submitted with Request for Continued Examination (RCE)
 - ii. ☒ Communication Submitted with Request for Continued Examination (RCE) Concerning Priority Claim

2. Miscellaneous

- a. ☒ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of 3 months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required)
- b. ☐ Other _____

3. Fees

The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed

- a. ☒ The Director is hereby authorized to charge the required fees, or credit any overpayments, to Pennie & Edmonds LLP Deposit Account No. 16-1150, including:
 - i. ☒ RCE fee required under 37 C.F.R. § 1.17(e), estimated to be \$ 740.00
 - ii. ☒ Three (3) month suspension of action fee under 37 C.F.R. § 1.17(i), estimated to be \$ 130.00

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Seth A. Watkins
For: Brian M. Rothery
 Seth A. Watkins Reg. No. 47,169
 For: Brian M. Rothery Reg. No. 35,340

July 11, 2002
 Dated

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Box RCE, Washington, DC 20231, or by facsimile transmitted to fax no. 1-703- to the U.S. Patent and Trademark Office on the date indicated below.

Name (Print/Type)	Registration No. (Attorney/Agent)
Signature	Date

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND Fees and Completed Forms to the following address: Commissioner for Patents, Box RCE, Washington, DC 20231.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: D. PAUL *et al.*

Application No.: 09/828,625

Group Art Unit: 3738

Filed: April 9, 2001

Examiner: S. Jackson

For: INTERVERTEBRAL ALLOGRAFT Attorney Docket No.: 8932-295
SPACER

**COMMUNICATION SUBMITTED WITH REQUEST FOR
CONTINUED EXAMINATION (RCE) CONCERNING PRIORITY CLAIM**

Box RCE

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Priority claims of the present application currently are as follows:

- (1) continuation of U.S. Patent Application No. 09/363,844, filed July 30, 1999, now U.S. Patent No. 6,258,125 B1, which claims the benefit under 35 U.S.C. § 119(e) of Provisional Application No. 60/095,209, filed August 3, 1998; and
- (2) continuation-in-part of U.S. Patent Application No. 09/219,439, filed December 23, 1998, now U.S. Patent No. 6,143,033, which in turn claims the benefit under 35 U.S.C. § 119(e) of Provisional Application No. 60/073,271, filed on January 30, 1998 and Provisional Application No. 60/095,425, filed on August 5, 1998.

It has come to the attention of Applicants that the above-referenced priority claim may not yet be perfected in the present application, in that U.S. Patent No. 6,258,125 B1 does not claim the benefit under 35 U.S.C. § 120 of U.S. Patent Application No. 09/219,439, filed December 23, 1998, now U.S. Patent No. 6,143,033, which in turn claims the benefit under 35 U.S.C. § 119(e) of Provisional Application No. 60/073,271, filed on January 30, 1998 and Provisional Application No. 60/095,425, filed on August 5, 1998. In addition, Applicants have discovered an error in the priorities listed in Section II of the

Petition to Make Special filed April 9, 2001. The correct priorities were set forth in the fee transmittal sheet originally filed with the present application.

Applicants have filed concurrently herewith a Request for Continued Examination (RCE), in part, to suspend action on the present application so that a reissue application of U.S. Patent No. 6,258,125 B1 can be filed to claim priority as noted above. Applicants will make the filing of such reissue application of record in the present application when the reissue application has been filed. Applicants believe that by correcting the priority claim in U.S. Patent No. 6,258,125 B1, the priority claim in the present application will be perfected.

No fee is believed to be due for this submission. Should any fees be required, however, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Seth A. Watkins

Date July 11, 2002

For: Brian M. Rothery

Seth A. Watkins

Reg. No. 47,169

For: Brian M. Rothery

Reg. No. 35,340

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: D. PAUL *et al.*

Application No.: 09/828,625

Group Art Unit: 3738

Filed: April 9, 2001

Examiner: S. Jackson

For: INTERVERTEBRAL ALLOGRAFT
SPACER

Attorney Docket No.: 8932-295

FEE TRANSMITTAL SHEET

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The fee required to be filed with the accompanying amendment of even date herewith concerning the above-identified application has been estimated to be \$600.

The claim amendment fee has been estimated as shown below:

	(Col. 1)		(Col. 2)		(Col. 3)	SMALL ENTITY		OTHER THAN A SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO PREVIOUSLY PAID FOR		PRESENT EXTRA	RATE	ADDIT. FEE	OR	ADDIT. FEE
TOTAL	44	MINUS	20	=	24	× 9	\$	× 18	\$ 432.00
INDEP.	5	MINUS	3	=	2	× 42	\$	× 84	\$ 168.00
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM						140	\$	280	\$
						TOTAL	\$	OR TOTAL	\$ 600.00

Please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.
A copy of this sheet is enclosed.

Respectfully submitted,

Seth A. Watkins
FOR: *Brian M. Rothery*

Date July 11, 2002

For: Seth A. Watkins Reg. No. 47,169
Brian M. Rothery Reg. No. 35,340

Enclosure

PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, DC 20006

(202) 496-4400

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: D. PAUL *et al.*

Application No.: 09/828,625

Group Art Unit: 3738

Filed: April 9, 2001

Examiner: S. Jackson

For: INTERVERTEBRAL ALLOGRAFT Attorney Docket No.: 8932-295
SPACER

**AMENDMENT SUBMITTED WITH
REQUEST FOR CONTINUED EXAMINATION (RCE)**

Box RCE
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Following the Notice of Allowance dated April 11, 2002, Applicants submit a Request for Continued Examination (RCE) along with this Amendment. A clean copy of the claims that will be pending as of entry of the instant amendment is attached hereto as Exhibit A.

Please enter the following amendments and remarks into the file of the above-identified application:

In the Claims

Please add the following claims:

21. (New) An intervertebral implant comprising at least one piece of allogenic bone provided with a hollow interior space, the implant having top and bottom surfaces configured and adapted in use to face the end plates of adjacent vertebrae, wherein the top and bottom surfaces include a plurality of teeth provided in a plurality of adjacent rows, and wherein at least a portion of the teeth have a pyramidal shape defined by four sides forming an acute angle with respect to the respective top and bottom surfaces of the implant.

22. (New) The implant of claim 21, wherein the top and bottom surfaces each have an opening communicating with the hollow interior space.

23. (New) The implant of claim 21, wherein the interior space and openings form a substantially cylindrical chamber.

24. (New) The implant of claim 21, wherein the angle formed from the tip of the pyramidal teeth to a base where the sides meet with the respective top and bottom surfaces is between about 45° and about 75°.

25. (New) The implant of claim 24, wherein the angle is approximately 60°.

26. (New) The implant of claim 21, wherein the implant is substantially symmetrical about a mid-plane of the implant.

27. (New) The implant of claim 26, wherein the implant has a wedge shaped profile such that the top surface is inclined with respect to the bottom surface.

28. (New) The implant of claim 27, wherein the angle of inclination between the top surface and the midplane is between about 4° and about 15°.

29. (New) The implant of claim 28, wherein the top and bottom surfaces are substantially flat planar surfaces.

30. (New) The implant of claim 28, wherein the top and bottom surfaces are curved surfaces.

31. (New) The implant of claim 21, wherein the implant has first and second sides and a gradual decrease in height from the first side to the second side.

32. (New) The implant of claim 21, wherein the implant has at least one rounded edge between the top and bottom surfaces to facilitate insertion of the implant.

33. (New) The implant of claim 21, further comprising at least one channel adapted and configured to receive a surgical instrument.

34. (New) The implant of claim 33, wherein the at least one channel extends along the entire length of the implant.

35. (New) The implant of claim 34, wherein the at least one channel is substantially smooth and devoid of teeth.

36. (New) The implant of claim 35, further comprising a pair of parallel channels adapted and configured to receive a single surgical instrument.

37. (New) The implant of claim 36, further comprising at least two lateral sides wherein the channels are formed in the two lateral sides.

38. (New) The implant of claim 21, wherein the implant is formed of more than one piece of bone.

39. (New) The implant of claim 38, wherein the pieces of bone are arranged side by side and the top and bottom surfaces are formed of more than one piece of bone.

40. (New) The implant of claim 21, wherein the teeth are arranged to cover substantially the entire top and bottom surfaces.

41. (New) An intervertebral implant formed of at least one piece of allogenic bone provided with a hollow substantially cylindrical interior space, the implant comprising: a mid-plane about which the implant is substantially symmetrical;

top and bottom surfaces configured and adapted in use to face the end plates of adjacent vertebrae, the top and bottom surface each having an opening communicating with the substantially cylindrical space, and the top surface being inclined in a range between about 4° and 15° with respect to the mid-plane;

at least two substantially smooth parallel channels adapted and configured to receive a surgical instrument; and

at least one rounded edge between the top and bottom surfaces to facilitate insertion of the implant;

wherein the top and bottom surfaces comprise a plurality of teeth provided in a plurality of adjacent rows, and further wherein the teeth are defined by four sides, at least three of the sides forming an acute angle with respect to the respective top and bottom surfaces.

42. (New) The implant of claim 41, wherein the top and bottom surfaces are substantially flat planar surfaces.

43. (New) The implant of claim 41, wherein the top and bottom surfaces are substantially flat in a first direction and curved in a second direction.

44. (New) The implant of claim 41 formed of more than one piece of allogenic bone arranged side by side and adapted and configured such that the top and bottom surfaces are formed of more than one piece of bone.

A Fee Transmittal Sheet is attached for the presentation of 24 new claims.
Should any additional fees be required, however, please charge such fees to Pennie &
Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date July 11, 2002

Seth A. Watkins

FOR: Brian M. Rothery

Seth A. Watkins
For: Brian M. Rothery

Reg. No. 47,169
Reg. No. 35,340

PENNIE & EDMONDS LLP
1667 K Street, N.W.
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Attachments

**EXHIBIT A - CLEAN COPY OF THE CLAIMS PENDING AS OF ENTRY
OF AMENDMENT FILED JULY 11, 2002 FOR APPLN. SERIAL NO. 09/828,625**

1. (Unamended) An intervertebral implant comprising a plug of allogenic bone conforming in size and shape with a portion of the end plates of adjacent vertebrae, wherein the top and bottom surfaces of the implant include a plurality of teeth provided in at least a two dimensional array with the teeth being spaced apart from one another for interlocking with the adjacent vertebrae, and wherein the teeth have a pyramidal shape profile defined by four sides forming an acute angle with respect to the respective top and bottom surfaces of the implant.
2. (Unamended) The implant of claim 1 wherein the implant has an interior space for receiving osteoconductive material to promote the formation of new bone.
3. (Unamended) The implant of claim 2 wherein the osteoconductive material comprises bone chips.
4. (Unamended) The implant of claim 1 wherein the angle formed from the tip of the teeth to a base where the sides meet with the respective top and bottom surfaces is approximately 60 degrees.
5. (Unamended) The implant of claim 1 wherein the implant has a wedge-shaped profile to help restore disc height and spine curvature.
6. (Unamended) The implant of claim 1 wherein the implant is formed of more than one piece of allogenic bone.
7. (Unamended) The implant of claim 1 wherein the top and bottom surfaces are curved surfaces.

8. (Unamended) The implant of claim 1 wherein the teeth are integral with the top and bottom surfaces.
9. (Unamended) The implant of claim 1 wherein the teeth on the top and bottom surfaces are interrupted to form a channel to receive an insertion instrument for placing the implant.
10. (Unamended) A method for restoring disc height between adjacent vertebrae having facing endplates, the method comprising:
removing at least a portion of a disc located between the adjacent vertebrae;
distracting an inner space between the facing endplates; and
inserting the implant of claim 1 into the distracted inner space.
11. (Unamended) The method of claim 10 further comprising measuring a distance between the adjacent vertebrae with a preoperative lateral radiograph to determine an implant height.
12. (Unamended) The method of claim 10 wherein a distractor is used to distract the inner space.
13. (Unamended) The method of claim 12 further comprising inserting a trial spacer implant to determine an implant height.
14. (Unamended) The method of claim 10 wherein the implant further includes an interior space and the method further comprises placing osteoconductive material into the interior space of the implant.
15. (Unamended) An implant for restoring disc height between adjacent vertebrae having facing endplates comprising an annular plug of allogenic bone surrounding an interior space, the plug having top and bottom surfaces configured and adapted in use to face the endplates of adjacent vertebrae, wherein the top and bottom surfaces include a plurality of

teeth provided in at least a two dimensional array, and wherein the teeth have a pyramidal shape defined by four sides forming an acute angle with respect to the respective top and bottom surfaces of the implant.

16. (Unamended) The implant of claim 15 wherein the angle formed from the tip of the teeth to a base where the sides meet with the respective top and bottom surfaces is approximately 60 degrees.

17. (Unamended) The implant of claim 16 wherein the implant has a wedge-shaped profile to help restore disc height and spine curvature.

18. (Unamended) The implant of claim 17 wherein the top and bottom surfaces are curved surfaces.

19. (Unamended) The implant of claim 16 wherein the teeth are integral with the top and bottom surfaces.

20. (Unamended) The implant of claim 15 wherein the implant is formed of more than one piece of allogenic bone.

21. (New) An intervertebral implant comprising at least one piece of allogenic bone provided with a hollow interior space, the implant having top and bottom surfaces configured and adapted in use to face the end plates of adjacent vertebrae, wherein the top and bottom surfaces include a plurality of teeth provided in a plurality of adjacent rows, and wherein at least a portion of the teeth have a pyramidal shape defined by four sides forming an acute angle with respect to the respective top and bottom surfaces of the implant.

22. (New) The implant of claim 21, wherein the top and bottom surfaces each have an opening communicating with the hollow interior space.

23. (New) The implant of claim 21, wherein the interior space and openings form a substantially cylindrical chamber.

24. (New) The implant of claim 21, wherein the angle formed from the tip of the pyramidal teeth to a base where the sides meet with the respective top and bottom surfaces is between about 45° and about 75° .

25. (New) The implant of claim 24, wherein the angle is approximately 60° .

26. (New) The implant of claim 21, wherein the implant is substantially symmetrical about a mid-plane of the implant.

27. (New) The implant of claim 26, wherein the implant has a wedge shaped profile such that the top surface is inclined with respect to the bottom surface.

28. (New) The implant of claim 27, wherein the angle of inclination between the top surface and the midplane is between about 4° and about 15° .

29. (New) The implant of claim 28, wherein the top and bottom surfaces are substantially flat planar surfaces.

30. (New) The implant of claim 28, wherein the top and bottom surfaces are curved surfaces.

31. (New) The implant of claim 21, wherein the implant has first and second sides and a gradual decrease in height from the first side to the second side.

32. (New) The implant of claim 21, wherein the implant has at least one rounded edge between the top and bottom surfaces to facilitate insertion of the implant.

33. (New) The implant of claim 21, further comprising at least one channel adapted and configured to receive a surgical instrument.

34. (New) The implant of claim 33, wherein the at least one channel extends along the entire length of the implant.

35. (New) The implant of claim 34, wherein the at least one channel is substantially smooth and devoid of teeth.

36. (New) The implant of claim 35, further comprising a pair of parallel channels adapted and configured to receive a single surgical instrument.

37. (New) The implant of claim 36, further comprising at least two lateral sides wherein the channels are formed in the two lateral sides.

38. (New) The implant of claim 21, wherein the implant is formed of more than one piece of bone.

39. (New) The implant of claim 38, wherein the pieces of bone are arranged side by side and the top and bottom surfaces are formed of more than one piece of bone.

40. (New) The implant of claim 21, wherein the teeth are arranged to cover substantially the entire top and bottom surfaces.

41. (New) An intervertebral implant formed of at least one piece of allogenic bone provided with a hollow substantially cylindrical interior space, the implant comprising: a mid-plane about which the implant is substantially symmetrical;

top and bottom surfaces configured and adapted in use to face the end plates of adjacent vertebrae, the top and bottom surface each having an opening communicating with the substantially cylindrical space, and the top surface being inclined in a range between about 4° and 15° with respect to the mid-plane;

at least two substantially smooth parallel channels adapted and configured to receive a surgical instrument; and

at least one rounded edge between the top and bottom surfaces to facilitate insertion of the implant;

wherein the top and bottom surfaces comprise a plurality of teeth provided in a plurality of adjacent rows, and further wherein the teeth are defined by four sides, at least three of the sides forming an acute angle with respect to the respective top and bottom surfaces.

42. (New) The implant of claim 41, wherein the top and bottom surfaces are substantially flat planar surfaces.

43. (New) The implant of claim 41, wherein the top and bottom surfaces are substantially flat in a first direction and curved in a second direction.

44. (New) The implant of claim 41 formed of more than one piece of allogenic bone arranged side by side and adapted and configured such that the top and bottom surfaces are formed of more than one piece of bone.